IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY, GENEOHM SCIENCES CANADA, INC. and HANDYLAB, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
NEUMODX MOLECULAR, INC.,	)	**DEMAND FOR JURY TRIAL**
Defendant.	)	

COMPLAINT

Becton, Dickinson and Company, GeneOhm Sciences Canada, Inc. (collectively "BD"), and HandyLab, Inc. ("HandyLab" and collectively with BD, "Plaintiffs"), by and through their attorneys, hereby allege for their Complaint against NeuMoDx Molecular, Inc. ("NeuMoDx" or "Defendant") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*, including 35 U.S.C. § 271.

2. Plaintiffs bring this action to seek relief for NeuMoDx's infringement of Plaintiffs' rights arising under the Patent Laws of the United States 35 U.S.C. § 1, *et. seq.*, from U.S. Patent Nos. 8,273,308; 8,703,069; 7,998,708; 8,323,900; 8,415,103; and 8,709,787 (collectively "the Asserted Patents").

THE PARTIES

3. HandyLab, a wholly owned subsidiary of Becton, Dickinson and Company, is a corporation organized and existing under the laws of Delaware. HandyLab's officers and

directors control, direct, and coordinate the corporation's activities from Franklin Lakes, NJ 07417. HandyLab is the current owner by assignment of the Asserted Patents.

4. Becton, Dickinson and Company is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 1 Becton Drive, Franklin Lakes, NJ 07417. GeneOhm Sciences Canada, Inc., a wholly owned subsidiary of Becton, Dickinson and Company, is a corporation organized and existing under the laws of Canada, with its principal place of business 2555 Boul du Parc-Technologique Québec G1P4S5 Canada. BD is the exclusive licensee of the Asserted Patents.

5. Upon information and belief, NeuMoDx is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1250 Eisenhower Place, Ann Arbor, Michigan 48108-3281.

JURISDICTION AND VENUE

6. Plaintiffs bring this action for patent infringement by NeuMoDx arising under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over NeuMoDx because, *inter alia*, NeuMoDx is incorporated in Delaware, and committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement that have led to foreseeable harm and injury to Plaintiffs in Delaware. Moreover, NeuMoDx has substantial contacts with the forum as a consequence of being incorporated in Delaware and, upon information and belief, conducting business in Delaware.

8. Venue is proper in this District under 28 U.S.C. § 1400(b) because NeuMoDx is a Delaware corporation that, upon information and belief, conducts business in Delaware.

Delaware is also the most convenient forum, and litigating this action in Delaware is in the interests of justice, under 28 U.S.C. § 1404(a).

FACTUAL ALLEGATIONS

Background

9. BD is a leading global medical technology company that is advancing the world of health by improving medical discovery, diagnostics, and the delivery of care. BD leads in patient and healthcare worker safety and the technologies that enable medical research and clinical laboratories. BD provides innovative solutions, including products that help advance medical research, produces new drugs and vaccines, and enhances the diagnosis of infectious diseases and cancer.

10. In 2009, BD acquired HandyLab, a small biotechnology company developing bench-top devices for fast and early detection of diseases. HandyLab was originally founded in 1999 in Ann Arbor, Michigan by Kalyan Handique and Sundaresh Brahmasandra. Jeffrey Williams joined HandyLab as its CEO in 2004.

11. BD recognized HandyLab's emerging and nascent technology as promising, and in 2009, paid a substantial sum to acquire HandyLab, further develop that technology, integrate it with BD's own technology and expertise, and ultimately launch a diagnostics platform. In press releases, Williams stated that the "exclusive collaboration with BD represents an important step forward in expanding the utility" of HandyLab's platform, and that the collaboration with BD would "provide diagnostic laboratories with a broad molecular test menu on one of the industry's most advanced automation platform." *See* **Exhibit 7**. Funders of HandyLab called it "a big win for everybody." *See* **Exhibit 8**. As part of the acquisition, BD was granted an exclusive license to HandyLab's patented technologies as reflected in the Asserted Patents.

12. BD's acquisition of HandyLab set the stage for BD's next generation of molecular diagnostics platforms. BD invested heavily in developing the HandyLab technology, made numerous innovative improvements, leveraged its own related diagnostics technologies, know-how and expertise, and creating and launching the BD MAX™ System—an automated molecular system designed to perform a broad range of molecular tests. The BD MAX™ System is a fully-integrated and fully-automated platform, incorporating clinical sample preparation, nucleic acid extraction, as well as microfluidic real-time polymerase chain reaction ("PCR") amplification and detection in a single diagnostic system. The BD MAX™ System runs multiple specimen types and assays in a single run, providing highly sensitive and specific results in just a few hours. The system leverages a versatile menu and streamlined workflow to reduce total costs, and at short turnaround times that facilitate fast treatment decisions.

13. In 2012, Williams founded a company called "Molecular Systems Corp.," which ultimately became NeuMoDx. Months later, Brahmasandra, who had taken the position of Vice President of R&D Assay Development at BD after the HandyLab acquisition, joined NeuMoDx as President. Williams and Brahamsandra are named inventors on two of the Asserted Patents, and have long been aware of the inventions and patented technologies of the Asserted Patents.

14. NeuMoDx has been and is today utilizing the same patented technologies that BD acquired from HandyLab and developed into the BD MAX™ System. NeuMoDx has infringed and continues to infringe the Asserted Patents by making, using (including during research and development activities and product testing), offering for sale, selling and/or importing at least NeuMoDx's molecular diagnostics products, or inducing or contributing to such acts.

15. NeuMoDx's infringement has been and continues to be willful. On information and belief, prior to and no later than September 2017, NeuMoDx conducted a review of third-

party patents and identified the Asserted Patents as relevant to NeuMoDx's molecular diagnostics products. On information and belief, at least as of September 2017, NeuMoDx also knew or should have known that NeuMoDx's molecular diagnostics products were infringing but that it was acting despite an objectively high likelihood that its conduct would infringe the Asserted Patents. Nevertheless, NeuMoDx continued its willful and deliberate infringement of the Asserted Patents.

16. BD's past and future success as a company depends on its targeted investments in innovations that align with BD's business. BD integrates technologies across different applications to create next-generation innovations, including the BD MAX™ System for fully-integrated and fully-automated molecular diagnostics. BD's success depends on protecting those innovations, including the inventions claimed in the Asserted Patents.

17. As the direct and proximate result of NeuMoDx's conduct, Plaintiffs have suffered, and if NeuMoDx's conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

The Asserted Patents

18. U.S. Patent No. 8,273,308 (the "'308 Patent"), entitled "Moving Microdroplets in a Microfluidic Device," was duly and legally issued on September 25, 2012 to inventors Kalyan Handique and Gene Parunak. A true and correct copy of the '308 Patent is attached as **Exhibit 1**.

19. U.S. Patent No. 8,703,069 (the "'069 Patent"), entitled "Moving Microdroplets in a Microfluidic Device" was duly and legally issued on April 22, 2014 to inventors Kalyan Handique and Gene Parunak. A true and correct copy of the '069 Patent is attached as **Exhibit 2**.

20. U.S. Patent No. 7,998,708 (the "'708 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" was duly and legally issued on August 16, 2011 to inventors Kalyan Handique, Sundaresh N. Brahmasandra, Karthik Ganesan, and Jeff Williams. A true and correct copy of the '708 Patent is attached as **Exhibit 3**.

21. U.S. Patent No. 8,323,900 (the "'900 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" was duly and legally issued on December 4, 2012 to inventors Kalyan Handique, Sundaresh N. Brahmasandra, Karthik Ganesan, and Jeff Williams. A true and correct copy of the '900 Patent is attached as **Exhibit 4**.

22. U.S. Patent No. 8,415,103 (the "'103 Patent"), entitled "Microfluidic Cartridge" was duly and legally issued on April 9, 2013 to inventor Kalyan Handique. A true and correct copy of the '103 Patent is attached as **Exhibit 5**.

23. U.S. Patent No. 8,709,787 (the "'787 Patent"), entitled "Microfluidic Cartridge and Method of Using Same" was duly and legally issued on April 29, 2014 to inventor Kalyan Handique. A true and correct copy of the '787 Patent is attached as **Exhibit 6**.

24. On information and belief, NeuMoDx had knowledge of the '708 and '900 Patents in 2012, the same year that NeuMoDx was founded, at least as a result of Williams' and Brahmasandra's being named co-inventors of those patents. NeuMoDx also had knowledge of the '308, '708, '900, '103, and '787 Patents, as evidenced by numerous citations by NeuMoDx to these patents during the prosecution of NeuMoDx patents. For example, on May 28, 2014, the

'308, '708, '900, and '103 Patents were cited in an Information Disclosure Statement submitted during the prosecution of NeuMoDx patent, U.S. Patent No. 9,050,594, and those four patents were subsequently cited or discussed in the prosecution of at least U.S. Patent No. 9,382,532, U.S. Patent No. 9,738,887, U.S. Patent No. 9,433,940, and U.S. Patent No. 9,339,812. On June 2, 2014, the '787 Patent was cited in an Office Action by the patent examiner during the prosecution of NeuMoDx patent, U.S. Patent No. 9,101,930. On information and belief, prior to and no later than September 2017, NeuMoDx conducted a third-party patent review and identified the Asserted Patents as relevant to NeuMoDx's molecular diagnostics products. On information and belief, NeuMoDx also had knowledge of at least the '708 and '900 Patents at least of December 2018, when petitions for inter partes review proceedings, IPR2019-00488 and IPR2019-00490, were filed against those patents. NeuMoDx also had knowledge of the Asserted Patents at least as a result of BD's January 2, 2019 email to Williams attaching a spreadsheet identifying U.S. Patent Nos. 8,273,308, 8,703,069, 7,998,708, 8,323,900, and 8,415,103, as well as patent titles, exemplary claims, and expiration dates. *See* **Exhibit 9**.

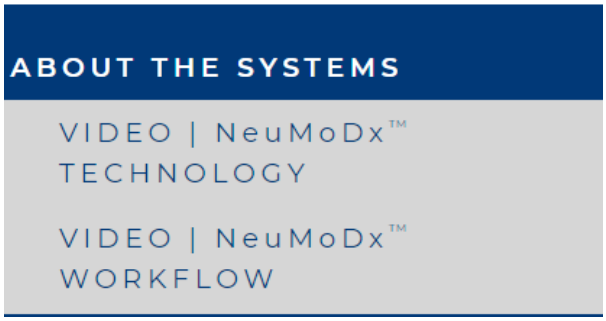
NEUMODX'S INFRINGING PRODUCTS

25. Exemplary infringement charts, attached as **Exhibits 34-39,** detail NeuMoDx's infringement of the Asserted Patents. These descriptions are not intended to limit Plaintiffs' right to amend, supplement, or modify these descriptions or any other analysis, description, or claim chart or allege that other activities of NeuMoDx infringe the identified claims or any other claims of these patents or any other patents.

26. NeuMoDx manufactures, uses, sells, offers for sale and/or imports molecular diagnostics systems, instruments, test strips, and reagents (the "Accused Products" or "Molecular Diagnostics Products"). The Accused Products include NeuMoDx's NeuMoDx™

288 Molecular System (Product Code 500200) and NeuMoDx™ 96 Molecular System (Product Code 50100), and any products or components that are imported, made, used, sold, and/or offered for sale by or on behalf of NeuMoDx in connection with and/or as part of NeuMoDx's NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems, or any other NeuMoDx products that embody like functionality, including without limitation the NeuMoDx™ Cartridge (Product Code 100100); NeuMoDx™ GBS Test Strip (Product Code 200400); NeuMoDx™ LDT Master Mix, DNA (Product Code 210100); NeuMoDx™ LDT Master Mix, RNA (Product Code 310100); and NeuMoDx™ LDT Primer/Probe Strip (Product Code). NeuMoDx manufactures, uses, sells, offers for sale and/or imports the Accused Products as indicated on its website, and markets the Accused Products as competing with the BD MAX™ System.[1]

27. The NeuMoDx website links to videos that illustrate the form and function of the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems, including: (1) a video directed to the NeuMoDx™ technology, which links to a Vimeo hyperlink, https://vimeo.com/281470603, and (2) a video directed to the NeuMoDx™ workflow, which links to a Vimeo hyperlink, https://vimeo.com/299307936.[2]



[1] *See* https://www.neumodx.com/our-products/.

[2] *See* https://www.neumodx.com/our-solutions/.

28. NeuMoDx also marks its products sold on its website by patent number.[3] NeuMoDx marks its cartridge products with the following patent numbers: U.S. Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430; as well as AU Patent No. 2013221701; and JP Patent No. 6061313. NeuMoDx marks its P02 (overall system and method) products with the following patent numbers: U.S. Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888; as well as CN Patent No. ZL 2013 8 00092863. NeuMoDx marks its extraction plate products with the following patent numbers: U.S. Patent Nos. 9,382,532, and 9,540,636. NeuMoDx marks its XPCR module products with the following patent numbers: U.S. Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.

NeuMoDx molecular

PATENTS

Product	Patents
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.
P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. ZL 2013 8 00092863.
EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636.
XPCR MODULE	US Patent Nos. 9,499,896; 9,539,576; 9,637,775; and 10,093,963.

COUNT 1
(INFRINGEMENT OF THE '308 PATENT)

29. Plaintiffs incorporate each of the above paragraphs as though fully set forth herein.

30. On information and belief, NeuMoDx directly or through the actions of its employees, agents, distributors, divisions, and/or subsidiaries, has infringed and continues to

[3] *See* https://www.neumodx.com/patents/.

infringe, one or more of the claims of the '308 Patent, including at least claims 1, 18, and 19, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or importing the Accused Products within the United States, and/or inducing or contributing to such acts, without authority.

31. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

Claim 1. A system, comprising:
a microfluidic device;
a computer-controlled heat source; and
a detector;
wherein the microfluidic device comprises:
an upstream channel;
a DNA manipulation module located downstream from the upstream channel;
a DNA manipulation zone within the DNA manipulation module and configured to perform PCR amplification of a sample;
a first valve disposed within the DNA manipulation module upstream of the DNA manipulation zone;
a second valve disposed within the DNA manipulation module downstream of the DNA manipulation zone; and
a vent disposed within the DNA manipulation module and separated from the upstream channel by the first and second valves;
a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone when amplification of the sample occurs, wherein the only ingress to and egress from the DNA manipulation zone is through the first and second valves, and wherein the computer-controlled heat source is in thermal contact with the DNA manipulation zone; and
wherein the detector is configured to identify one or more polynucleotides within the DNA manipulation zone.

32. The Accused Products also meet each element of, and infringe, claim 18, which states:

Claim 18. A device, comprising:
a microfluidic process module;

a computer-controlled heat source; and
a detector;
wherein the microfluidic process module comprises:
a zone configured to receive a sample and perform amplification of the sample;
a first valve upstream of the zone;
a second valve downstream of the zone; and
a vent separated from the first valve by the second valve;
a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the zone when amplification of the sample occurs in the zone, wherein the only ingress to and egress from the zone is through the first and second valves;
wherein the computer-controlled heat source is in thermal contact with the zone; and
wherein the detector is configured to identify one or more polynucleotides within the zone.

33. The Accused Products also meet each element of, and infringe, claim 19, which states:

Claim 19. A system, comprising:
a microfluidic device;
a computer-controlled heat source; and
a detector;
wherein the microfluidic device comprises:
an upstream channel;
a DNA manipulation zone located downstream from the upstream channel and configured to perform PCR amplification of a sample;
a first valve disposed upstream of the DNA manipulation zone; and
a second valve disposed downstream of the DNA manipulation zone;
a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone and to isolate and confine the sample to a region between the first and second valves accessible to the detector, wherein the only ingress to and egress from the region accessible to the detector is through the first and second valves; and
wherein the computer-controlled heat source is in thermal contact with the DNA manipulation zone and wherein the detector is configured to identify one or more polynucleotides within the DNA manipulation zone.

34. NeuMoDx infringes each element of claims 1, 18, and 19 of the ’308 Patent. NeuMoDx’s own documents, publicly posted videos, and patents that are marked on its products show that the Accused Products infringe the claims of the ‘308 Patent. As an example, U.S. Patent No. 8,273,308 Preliminary and Exemplary Claim Chart, detailing NeuMoDx’s

infringement of these claims of the '308 Patent, is attached as **Exhibit 34**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of NeuMoDx infringe the identified claims or any other claims of the '308 Patent or any other patents. **Exhibit 34** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 34** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

35. NeuMoDx has also induced and currently induces infringement of the '308 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, NeuMoDx knows infringes the '308 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '308 Patent and of its infringement since at least September 2017. By providing its customers with the Accused Products and those instructions for use, NeuMoDx specifically intends that its customers infringe the '308 Patent.

36. NeuMoDx has contributorily infringed and currently contributorily infringes the '308 Patent under 35 U.S.C. § 271(c). NeuMoDx has designed the Accused Products specifically to be used in a manner as claimed in the '308 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '308 Patent, and especially made and adapted for use in a manner that infringes the '308 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. NeuMoDx has

knowledge of the '308 Patent and is aware that the Accused Products are especially made to be used in a system that infringes the '308 Patent.

37. NeuMoDx's infringement has been willful and deliberate because, on information and belief, NeuMoDx has known of the '308 Patent since at least September 2017 and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '308 Patent.

38. As the direct and proximate result of NeuMoDx's conduct, Plaintiffs have suffered, and if NeuMoDx's conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 2
(INFRINGEMENT OF THE '069 PATENT)

39. Plaintiffs incorporate each of the above paragraphs as though fully set forth herein.

40. On information and belief, NeuMoDx directly or through the actions of its employees, agents, distributors, divisions, and/or subsidiaries, has infringed and continues to infringe, one or more of the claims of the '069 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or importing the Accused Products within the United States, and/or inducing or contributing to such acts, without authority.

41. For example, the Accused Products and uses of the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A method of amplifying a nucleic acid-containing sample within a microfluidic device, the method comprising:
> moving the sample from an upstream channel of the microfluidic device into a DNA manipulation module located downstream of the upstream channel, the DNA manipulation module including a DNA manipulation zone configured to perform amplification of the sample, a first valve disposed upstream of the DNA manipulation zone, and a second valve disposed downstream of the DNA manipulation zone, the only ingress to and egress from the DNA manipulation zone being through the first valve and the second valve;
> receiving the sample in the DNA manipulation zone;
> closing the first valve and the second valve such that gas and liquid are prevented from flowing into or out of the DNA manipulation zone; and
> thermal cycling the sample in the DNA manipulation zone.

42. NeuMoDx infringes each element of claim 1 of the ’069 Patent. NeuMoDx’s own documents, publicly posted videos, and patents that are marked on its products show that the Accused Products infringe the claims of the ’069 Patent. As an example, U.S. Patent No. 8,703,069 Preliminary and Exemplary Claim Chart, detailing NeuMoDx’s infringement of these claims of the ’069 Patent, is attached as **Exhibit 35**. This chart is not intended to limit Plaintiffs’ right to modify the chart or allege that other activities of NeuMoDx infringe the identified claims or any other claims of the ’069 Patent or any other patents. **Exhibit 35** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 35** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

43. NeuMoDx has also induced and currently induces infringement of the ’069 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, NeuMoDx knows infringes the ’069 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code

100100). On information and belief, NeuMoDx has known of the '069 Patent and of its infringement since at least September 2017. By providing its customers with the Accused Products and those instructions for use, NeuMoDx specifically intends that its customers infringe the '069 Patent.

44. NeuMoDx has contributorily infringed and currently contributorily infringes the '069 Patent under 35 U.S.C. § 271(c). NeuMoDx has designed the Accused Products specifically to be used in a manner as claimed in the '069 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '069 Patent, and especially made and adapted for use in a manner that infringes the '069 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. NeuMoDx has knowledge of the '069 Patent and is aware that the Accused Products are especially made to be used in a system that infringes the '069 Patent.

45. NeuMoDx's infringement has been willful and deliberate because, on information and belief, NeuMoDx has known of the '069 Patent since at least September 2017 and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '069 Patent.

46. As the direct and proximate result of NeuMoDx's conduct, Plaintiffs have suffered, and if NeuMoDx's conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 3
(INFRINGEMENT OF THE '708 PATENT)

47. Plaintiffs incorporate each of the above paragraphs as though fully set forth herein.

48. On information and belief, NeuMoDx directly or through the actions of its employees, agents, distributors, divisions, and/or subsidiaries, has infringed and continues to infringe, one or more of the claims of the '708 Patent, including at least claims 1 and 33, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or importing the Accused Products within the United States, and/or inducing or contributing to such acts, without authority.

49. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** An apparatus, comprising:
> a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone;
> a receiving bay configured to receive the microfluidic cartridge;
> each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source maintains a substantially uniform temperature throughout the PCR reaction zone and thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone;
> a detector configured to detect the presence of an amplification product in the respective PCR reaction zone; and
> a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources.

50. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 33, which states:

> **Claim 33.** A method of carrying out PCR on a plurality of samples, the method comprising:

introducing the plurality of samples into a multi-lane microfluidic cartridge, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples;
moving the plurality of samples into the respective plurality of PCR reaction zones; and
amplifying polynucleotides contained with the plurality of samples in the PCR reaction zones while thermal cycling the PCR reaction zones, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.

51. NeuMoDx infringes each element of claims 1 and 33 of the '708 Patent. NeuMoDx's own documents, publicly posted videos, and patents that are marked on its products show that the Accused Products infringe the claims of the '708 Patent. As an example, U.S. Patent No. 7,998,708 Preliminary and Exemplary Claim Chart, detailing NeuMoDx's infringement of these claims of the '708 Patent, is attached as **Exhibit 36**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of NeuMoDx infringe the identified claims or any other claims of the '708 Patent or any other patents. **Exhibit 36** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 36** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

52. NeuMoDx has also induced and currently induces infringement of the '708 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, NeuMoDx knows infringes the '708 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '708 Patent and of its infringement since at least September 2017. By providing its customers with the Accused Products and those instructions for use, NeuMoDx specifically intends that its customers infringe the '708 Patent.

53. NeuMoDx has contributorily infringed and currently contributorily infringes the '708 Patent under 35 U.S.C. § 271(c). NeuMoDx has designed the Accused Products specifically to be used in a manner as claimed in the '708 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '708 Patent, and especially made and adapted for use in a manner that infringes the '708 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. NeuMoDx has knowledge of the '708 Patent and is aware that the Accused Products are especially made to be used in a system that infringes the '708 Patent.

54. NeuMoDx's infringement has been willful and deliberate because, on information and belief, NeuMoDx has known of the '708 Patent and of its infringement since at least September 2017 and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '708 Patent.

55. As the direct and proximate result of NeuMoDx's conduct, Plaintiffs have suffered, and if NeuMoDx's conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 4
(INFRINGEMENT OF THE '900 PATENT)

56. Plaintiffs incorporate each of the above paragraphs as though fully set forth herein.

57. On information and belief, NeuMoDx directly or through the actions of its employees, agents, distributors, divisions, and/or subsidiaries, has infringed and continues to infringe, one or more of the claims of the '900 Patent, including at least claims 1, 7, and 20, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or importing the Accused Products within the United States, and/or inducing or contributing to such acts, without authority.

58. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** An apparatus, comprising:
> a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone;
> a plurality of receiving bays, each receiving bay configured to receive one of the plurality of microfluidic cartridges;
> each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and maintains a substantially uniform temperature throughout the PCR reaction zone during each cycle;
> a detector configured to detect the presence of an amplification product in one or more PCR reaction zones; and
> a processor coupled to the detector and the heat sources, configured to control heating of one or more PCR reaction zones by the heat sources.

59. The Accused Products also meet each element of, and infringe, claim 7, which states:

> **Claim 7.** A device for carrying out PCR on a plurality of samples, the device comprising:
> a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone;
> a plurality of receiving bays, each receiving bay configured to receive one of the plurality of microfluidic cartridges;
> a separately controllable heat source thermally coupled to each PCR reaction zone, wherein the heat source is configured to thermal cycle the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone

and to maintain a substantially uniform temperature throughout the PCR reaction zone during each cycle;

a detector configured to detect the presence of an amplification product in one or more PCR reaction zones;

a processor coupled to the detector and a plurality of the separately controllable heat sources, configured to control heating of one or more PCR reaction zones by one or more of the plurality of separately controllable heat sources; and

an input device coupled to the processor and configured to permit concurrent or consecutive control of the plurality of multi-lane microfluidic cartridges.

60. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 20, which states:

Claim 20. A method of carrying out PCR on a plurality of samples, the method comprising:

introducing the plurality of samples into a plurality of multi-lane microfluidic cartridges, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples;

moving the plurality of samples into the respective plurality of PCR reaction zones; and

amplifying polynucleotides contained with the plurality of samples in the plurality of PCR reaction zones while thermal cycling the PCR reaction zones and maintaining a substantially uniform temperature throughout each PCR reaction zone during each cycle, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.

61. NeuMoDx infringes each element of claims 1, 7, and 20 of the '900 Patent. NeuMoDx's own documents, publicly posted videos, and patents that are marked on its products show that the Accused Products infringe the claims of the '900 Patent. As an example, U.S. Patent No. 8,323,900 Preliminary and Exemplary Claim Chart, detailing NeuMoDx's infringement of these claims of the '900 Patent, is attached as **Exhibit 37**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of NeuMoDx infringe the identified claims or any other claims of the '900 Patent or any other patents. **Exhibit 37** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 37** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

62. NeuMoDx has also induced and currently induces infringement of the '900 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, NeuMoDx knows infringes the '900 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '900 Patent and of its infringement since at least September 2017. By providing its customers with the Accused Products and those instructions for use, NeuMoDx specifically intends that its customers infringe the '900 Patent.

63. NeuMoDx has contributorily infringed and currently contributorily infringes the '900 Patent under 35 U.S.C. § 271(c). NeuMoDx has designed the Accused Products specifically to be used in a manner as claimed in the '900 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '900 Patent, and especially made and adapted for use in a manner that infringes the '900 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. NeuMoDx has knowledge of the '900 Patent and is aware that the Accused Products are especially made to be used in a system that infringes the '900 Patent.

64. NeuMoDx's infringement has been willful and deliberate because, on information and belief, NeuMoDx has known of the '900 Patent and of its infringement since at least September 2017 and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '900 Patent.

65. As the direct and proximate result of NeuMoDx's conduct, Plaintiffs have suffered, and if NeuMoDx's conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 5
(INFRINGEMENT OF THE '103 PATENT)

66. Plaintiffs incorporate each of the above paragraphs as though fully set forth herein.

67. On information and belief, NeuMoDx directly or through the actions of its employees, agents, distributors, divisions, and/or subsidiaries, has infringed and continues to infringe, one or more of the claims of the '103 Patent, including at least claims 1 and 15, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or importing the Accused Products within the United States, and/or inducing or contributing to such acts, without authority.

68. For example, the Accused Products and uses of the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:
> introducing the plurality of samples separately into a microfluidic cartridge;
> isolating the samples in the microfluidic cartridge;
> placing the microfluidic cartridge in thermal communication with an array of independent heaters; and

amplifying polynucleotides in the plurality of samples by independent application of successive temperature cycles to each sample.

69. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 15, which states:

Claim 15. A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:
introducing the plurality of samples in to a microfluidic cartridge, wherein the cartridge has a plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another;
moving the plurality of samples independently of one another into the respective plurality of reaction chambers;
isolating the samples within the plurality of reaction chambers;
placing the microfluidic cartridge in thermal communication with an array of independent heaters; and
amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers.

70. NeuMoDx infringes each element of claims 1 and 15 of the '103 Patent. NeuMoDx's own documents, publicly posted videos, and patents that are marked on its products show that the Accused Products infringe the claims of the '103 Patent. As an example, U.S. Patent No. 8,415,103 Preliminary and Exemplary Claim Chart, detailing NeuMoDx's infringement of these claims of the '103 Patent, is attached as **Exhibit 38**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of NeuMoDx infringe the identified claims or any other claims of the '103 Patent or any other patents. **Exhibit 38** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 38** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

71. NeuMoDx has also induced and currently induces infringement of the '103 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, NeuMoDx

knows infringes the '103 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '103 Patent and of its infringement since at least September 2017. By providing its customers with the Accused Products and those instructions for use, NeuMoDx specifically intends that its customers infringe the '103 Patent.

72. NeuMoDx has contributorily infringed and currently contributorily infringes the '103 Patent under 35 U.S.C. § 271(c). NeuMoDx has designed the Accused Products specifically to be used in a manner as claimed in the '103 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '103 Patent, and especially made and adapted for use in a manner that infringes the '103 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. NeuMoDx has knowledge of the '103 Patent and is aware that the Accused Products are especially made to be used in a system that infringes the '103 Patent.

73. NeuMoDx's infringement has been willful and deliberate because, on information and belief, NeuMoDx has known of the '103 Patent and of its infringement since at least September 2017 and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '103 Patent.

74. As the direct and proximate result of NeuMoDx's conduct, Plaintiffs have suffered, and if NeuMoDx's conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief.

Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 6
(INFRINGEMENT OF THE '787 PATENT)

75. Plaintiffs incorporate each of the above paragraphs as though fully set forth herein.

76. On information and belief, NeuMoDx directly or through the actions of its employees, agents, distributors, divisions, and/or subsidiaries, has infringed and continues to infringe, one or more of the claims of the '787 Patent, including at least claim 10, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or importing the Accused Products within the United States, and/or inducing or contributing to such acts, without authority.

77. For example, the Accused Products meet each element of, and infringe, claim 10, which states:

> **Claim 10.** A microfluidic substrate, comprising:
>
> a plurality of sample lanes, wherein each of the plurality of sample lanes comprises a microfluidic network having, in fluid communication with one another:
>
> an inlet;
>
> a first valve and a second valve;
>
> a first channel leading from the inlet, via the first valve, to a reaction chamber; and
>
> a second channel leading from the reaction chamber, via the second valve, to a vent,
>
> wherein the first valve and the second valve are configured to isolate the reaction chamber from the inlet and the vent to prevent movement of fluid into or out of the reaction chamber, wherein the first valve is spatially separated from the inlet and the second valve is spatially separated from the vent, wherein the reaction chamber, the first channel, and the second channel are formed in a first

side of the microfluidic substrate, wherein the inlet and the vent are formed in a second side of the microfluidic substrate opposite the first side, and wherein the first valve in each of the plurality of sample lanes is operated independently of any other first valve.

78. NeuMoDx infringes each element of claim 10 of the '787 Patent. NeuMoDx's own documents, publicly posted videos, and patents that are marked on its products show that the Accused Products infringe the claims of the '787 Patent. As an example, U.S. Patent No. 8,709,787 Preliminary and Exemplary Claim Chart, detailing NeuMoDx's infringement of these claims of the '787 Patent, is attached as **Exhibit 39**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of NeuMoDx infringe the identified claims or any other claims of the '787 Patent or any other patents. **Exhibit 39** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 39** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

79. NeuMoDx has also induced and currently induces infringement of the '787 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, NeuMoDx knows infringes the '787 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '787 Patent and of its infringement since at least September 2017. By providing its customers with the Accused Products and those instructions for use, NeuMoDx specifically intends that its customers infringe the '787 Patent.

80. NeuMoDx has contributorily infringed and currently contributorily infringes the '787 Patent under 35 U.S.C. § 271(c). NeuMoDx has designed the Accused Products

specifically to be used in a manner as claimed in the '787 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '787 Patent, and especially made and adapted for use in a manner that infringes the '787 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. NeuMoDx has knowledge of the '787 Patent and is aware that the Accused Products are especially made to be used in a system that infringes the '787 Patent.

81. NeuMoDx's infringement has been willful and deliberate because, on information and belief, NeuMoDx has known of the '787 Patent and of its infringement since at least September 2017 and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '787 Patent.

82. As the direct and proximate result of NeuMoDx's conduct, Plaintiffs have suffered, and if NeuMoDx's conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief, declaration and judgment that:

a. NeuMoDx has infringed the Asserted Patents;

b. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining NeuMoDx, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering for sale, selling in the United

States, or importing into the United States, the Accused Products, and any other product that infringes or induces or contributes to the infringement of the Asserted Patents, prior to the expiration date of the last to expire of those patents;

c. Plaintiffs are entitled to an award of damages pursuant to 35 U.S.C. § 284, including pre-judgment and post-judgment interest;

d. NeuMoDx's infringement of the Asserted Patents has been willful and Plaintiffs are entitled to enhanced damages up to and including trebling of the damages awarded to it;

e. Plaintiffs are entitled to their costs and reasonable expenses to the fullest extent permitted by law;

f. This case is exceptional pursuant to 35 U.S.C. § 285, and Plaintiffs are entitled to an award of attorneys' fees; and

g. Plaintiffs are entitled to other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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